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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/337,746	06/22/1999	GREGORY M. GLENN	PM-254811	9348

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

Office Action Summary	Application No.	Applicant(s)	
	09/337,746	GLENN ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *71,72,75-84,86,87 and 90-105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *71,72,75-84,86,87 and 90-105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, remarks, and Terminal Disclaimers, filed 12/21/04, are acknowledged. In view of the amendments, the previous rejections under the first paragraph of 35 U.S.C. 112, and under the second paragraph of 35 U.S.C. 112, have been withdrawn. In view of the amendments, and the Terminal Disclaimers, the previous rejections for obvious-type double patenting over U.S. Patent No. 6,797,276, U.S. Application No. 09/266,803, and U.S. Application No. 10/633,626 have been withdrawn.

2. Claims 71-72, 75-84, 86-87, 90-97, and newly added Claims 98-105, are pending and under examination.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321c may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. As set forth previously, Claims 71-72, 75-84, 86-87, 90-97, and newly added Claims 98-105 stand/are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 17 of copending Application No. 10/435,676. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method comprising inducing an immune response (TCI) comprising applying a formulation comprising an adjuvant or an antigen and an adjuvant.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments, filed 12/21/04, have been fully considered but they are not persuasive. Applicant argues that the claims of the '676 application require separate administration of antigen and adjuvant whereas the instant claims are drawn to the administration of a formulation.

It remains the Examiner's position that the aforementioned differences between the claims of the '676 application and the claims of the instant application do not render them patentably distinct. For example, the claims of the '676 application would encompass a method wherein the separate formulations are administered to the skin simultaneously at the same spot, thus, essentially comprising the administration of the formulation of the instant claims.

5. The following are new grounds for rejection necessitated by Applicant's amendment and submission of an additional application.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 71-72, 75-84, 86-87, 90-97, and newly added Claims 98-105, are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) a method employing "modified ADP-ribosylating exotoxins, B subunits of ADP-ribosylating exotoxins and mixtures thereof" and a method "wherein said formulation is hydrated such that delivery of an effective amount of said formulation occurs, wherein said effective amount of said formulation induces said antigen-specific immune response in said organism" (Claims 71 and 102),

B) a method comprising "an additional molecule which induces an antigen-specific immune response" (Claim 81),

C) a method wherein a "formulation is hydrated by

application of a patch" (Claims 96, 97, and 103),

D) a method wherein a "formulation is hydrated by disruption of the stratum corneum or superficial epidermis" (Claims 98 and 104),

E) a method wherein "said disruption is by one or more devices which disrupt only the stratum corneum or superficial epidermis" (Claims 99 and 105),

F) a method wherein "said formulation is hydrated by disruption of the stratum corneum or superficial epidermis" (Claim 100),

G) a method wherein "said disruption is by one or more devices which disrupt only the stratum corneum or superficial epidermis" (Claim 101),

H) a method comprising providing a formulation "without penetrating through the skin's dermis layer" (Claim 102).

Applicant states that no new matter has been added and indicates various cites throughout the specification for support.

Regarding A), the specification supports multiple antigens but not the multiple adjuvants (mixtures of ADP-ribosylating exotoxins and B subunits of ADP-ribosylating exotoxins) as claimed. Regarding the second new limitation of the claim, cites disclosing liquid formulations and materials to promote skin hydration, etc., provide insufficient support for a formulation that specifically hydrates and induces an antigen-specific immune response as claimed.

Regarding B), the specification does not disclose an additional molecule that induces an antigen-specific immune response as claimed.

Regarding C), the specification does not disclose a patch capable of hydration.

Regarding D-G), the specification at pages 49-50 discloses these limitations only in a context of enhancing the delivery of a solution.

Regarding H), the specification does not teach "without penetrating through the skin's dermis layer", but rather "without perforation of intact skin" (page 8).

8. Claims 71-72, 75-84, 86-87, 90-97, and newly added Claims 98-105 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1-92 of copending Application No.

10/895,323. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method comprising inducing an immune response (TCI) comprising applying a formulation comprising an antigen and an adjuvant including hydrating the skin and numerous other obvious permutations of the claimed method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Applicant is reminded of the duty to disclose all information relevant to patentability. As set forth in Applicant's declaration, Applicant acknowledges a responsibility under 37 CFR 1.56 to disclose all information known to Applicant material to patentability. Clearly, the disclosure of new applications reciting related claims falls under said responsibility.

10. No claim is allowed.

11. Applicant's amendment or action necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. Information regarding the status of an application may be obtained from the Patent Application

Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Inquiries of a general nature may also be directed to the Technology Center 1600 Receptionist at (571) 272-1600.

2/21/05

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600